

REMARKS

Claims 10, 12-14, 16-18, and 22-24 will be pending in the above-identified application upon entry of the present amendment. Claims 10, 13, and 14 have been amended to incorporate the subject matter of claim 19. As such, claim 19 has been cancelled herein. Thus, no new matter has been added. Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. § 103(a)

The Examiner has rejected claims 4, 6-8, 10, 12-14, and 16-19 under 35 U.S.C. § 103(a) as being unpatentable over Tamura et al. '447 (US 5,827,447) in view of Kobayashi et al. '440 (US 5,869,440).

Applicants respectfully traverse. Reconsideration and withdrawal of the outstanding rejection are respectfully requested based on the following considerations.

Legal Standard for Determining Prima Facie Obviousness

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

- (a) determining the scope and content of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating any evidence of secondary considerations.

Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Exemplary rationales that may support a conclusion of obviousness include:

- (a) combining prior art elements according to known methods to yield predictable results;
- (b) simple substitution of one known element for another to obtain predictable results;
- (c) use of known technique to improve similar devices (methods, or products) in the same way;
- (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (e) “obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success
- (f) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (g) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. *See* MPEP 2143.03.

Distinctions over the Cited References

Neither Tamura et al. ‘447 nor Kobayashi et al. ‘440 disclose the two step pH adjustment of the present invention, a reaction of Component (A) with Component (B1) in water at a pH of 8 to 12 and then an adjustment of the pH to 1 to 5. The mole ratio of Component (A) to Component (B1) is limited. The cited references also fail to disclose that “the reaction of (A) with (B1) in water at pH 8 to 12 is carried out at 5 to 50°C for 1 to 120 minutes.”

Relevant to this § 103(a) rejection, *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966) has provided the controlling framework for an obviousness analysis, wherein a proper analysis under § 103(a) requires consideration of the four *Graham* factors. One such factor includes the evaluation of any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. at 17, 148 USPQ at 467. In this regard, Applicants respectfully submit that the present invention has achieved unexpected results, whereby such

results rebut any asserted *prima facie* case of obviousness. See *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985). Also, the comparative showing need not compare the claimed invention with all of the cited prior art, but only with the closest prior art. See MPEP 716.02(b) and 716.02(e).

According to MPEP 2145, rebuttal evidence and arguments can be presented in a declaration under 37 CFR 1.132, *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995). Office personnel should consider all rebuttal arguments and evidence presented by Applicants. See, e.g., *Soni*, 54 F.3d at 750, 34 USPQ2d at 1687 (error not to consider evidence presented in the specification). Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties. *In re Dillon*, 919 F.2d 688, 692-93, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990).

Enclosed herewith is a 37 CFR § 1.132 Declaration of Noboru Matsuo, one of the present inventors. The Examiner is respectfully requested to review the enclosed Declaration of Noboru Matsuo as it provides strong evidence of the patentability of the present invention.

In the enclosed Declaration, the examples of the cited references which are closest to the present invention are compared to inventive examples. As shown in Table A of the enclosed Declaration, the number of remaining organisms with the inventive example is much less than the number with the comparative examples based on Example 11 of Tamura et al. '447. As such, the present invention is unexpectedly superior. The comparative examples strongly evidence that the cited references do not produce the results of the present invention.

Turning to Table B of the enclosed Declaration, Example 3-3 of the present specification is compared with Comparative Example 4 of Kobayashi et al. '440. However, the storage temperature and time of these examples were changed to show their criticality to the present invention. As shown in Table B of the enclosed Declaration, the number of remaining organisms with the inventive example is much less than the number with the comparative examples based on Comparative Example 4 of Kobayashi et al. '440. Furthermore, the number of remaining organisms when "the reaction of (A) with (B1) in water at pH 8 to 12 is carried out at 5 to 50°C for 1 to 120 minutes" as recited in the independent claims is much less than the number outside of these ranges. As such, the present invention is unexpectedly superior. The comparative

examples strongly evidence that the cited references do not produce the results of the present invention.

Thus, due to the unexpected results as achieved by the present invention, the rejection has been overcome. Reconsideration and withdrawal of this rejection are respectfully requested.

As stated in *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007), “rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” Furthermore, the mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *Id.* As described above, Applicants have shown that the present invention achieves unexpected and unpredictable results.

To establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be disclosed by the cited references. As discussed above, Tamura et al. ‘447 in view of Kobayashi et al. ‘440 fail to disclose all of the claim limitations of independent claims 10 and 13-14, and those claims dependent thereon. Accordingly, the combination of references does not render the present invention obvious.

Furthermore, the cited references or the knowledge in the art provide no reason or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed. Therefore, a *prima facie* case of obviousness has not been established, and withdrawal of the outstanding rejection is respectfully requested. Any contentions of the USPTO to the contrary must be reconsidered at present.

CONCLUSION

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case clearly indicating that each of claims 10, 12-14, 16-18, and 22-24 are allowed and patentable under the provisions of title 35 of the United States Code.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Chad M. Rink, Reg. No. 58,258 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: JAN 04 2010

Respectfully submitted,

By 

John W. Bailey

Registration No.: 32881

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road, Suite 100 East

P.O. Box 747

Falls Church, VA 22040-0747

703-205-8000

Attachment: 37 CFR § 1.132 Declaration of Noboru Matsuo